Access to Microfinance & Improved Implementation of Policy Reform
(AMIR Program)

Funded By U.S. Agency for International Development

Conformity with the WTO Agreement on Sanitary and Phytosanitary Measures- Food Aspects

Final Report

Deliverable for Policy Component, Task No. 4.4.28
Contract No. 278-C-00-98-00029-00

December 1999

This report was prepared by Mr. Anthony Whitehead, in collaboration with Chemonics International Inc., prime contractor to the U.S. Agency for International Development for the AMIR Program in Jordan.

INTRODUCTION:

The Government of the Hashemite Kingdom of Jordan is actively engaged in the assession procedures for membership to the World Trade Organization (WTO). This requires, inter alia, that food law and food control measures meet the terms of the technical agreements resulting from the Urugary Round of Multilateral Trade Negotiations of the General Agreement on Tariff and Trade (GATT), now the WTO. The technical agreements which are involved specifically are the Agreement on Sanitary and Phytosanitary Measures and the Technical Barriers to Trade Agreement. The governement of Jordan has always placed a high priority on taking the measures necessary within the limits of their technical and finanical resources to assure maintaining good health for its citizens. Assuring a high quality, safe and nutritious food supply to the people of Jordan is a major component of that programme. This is achieved through the implementation and enforcement of the Law No.(21) for the Year 1971, Public Health Law.

The government of Jordan has undertaken a review of its overall situation related to food control in preparation for assession to the WTO. The study revealed that the Public Health Law was in need of significant rewriting of the provisions related to food to update the law to current legal standards; that there is more than an ideal number of organizational units of government involved in food control; provisions of food law exist as fragments in a host of other and various existing laws; there is an absence of a dedicated and competant agency involved specifically with food control policy and control measures; and, inefficiencies exist in the current system of food control which need to be improved to meet international standards. A number of organizations and institutions from government and the private sector provided input into the study. A decision was made to draft a new food law specifically dedicated to food policy and control measures, including the legal establishment of a Public Institution of Food for the purpose of administering the law and establishing national food policy and control system.

This proposed draft food law is considered by the drafters to meet the government's objectives of protecting Jordanian consumers from unsafe and poor quality food and will prevent deceptive food trade practices through misrepresentation and misbranding resulting in economic fraud perpetrated on the public. This is expected to be achieved through close monitoring of foodstuffs to assure compliance with the procedures controling food production technologies and the latest developments in food safety, quality and nutrition; and, the legal establishment of an independent institution supervising domestically produced or imported food, to guarantee its safety, quality and nutritious value for consumption in all stages in life.

This consultant was contracted to review the existing Public Health Law (1971) and the draft proposed food law in accordance with the Scope of Work (SOW) stated below. Since this consultant is not qualified as an Attorney at Law, the review was made on the bases of its conceptual agreement with up-to-date international and national standards of the concepts of food law of most developed countries. The consultant's comments are based on a working and hands-on knowledge gained over 37 years of food law enforcement at the national and international level, and technical assistance in the preparation of food law and regulations for developing countries.

Summary of Findings

The consultant reviewed the existing Public Health Law (1971), (PHL) and the draft proposed food law in accordance with the Scope of Work listed below in this report. In summary, the Public Health Law was found to be limited in those aspects related to food and food control. It clearly reflects the vintage of the law in that it lacks any text which reflects the modern day approaches, procedures and concepts in modern food control practices and authorities. Although the regulations were not reviewed, it is presumed that the text required to keep the Pubic Health Law up-to-date may be elaborated as part of the regulations and would have to be viewed in their entirity to determine their exact impact. The limited articles in the PHL that relate to food are almost totally inadequate for conforming with the WTO/SPS Agreement and would require considerable amount of work in writing and re-writing text to amend the law to bring it into conformity. Time would be saved by starting by starting all over again with a new law.

In Reviewing the draft proposed new Food Law, it was determined that this law provides an adequate and well structured document to which some additions would be needed to make up for some ommissions; some text needs to be revised for further clarification and understanding; some specific additions may be required which address the principles and concepts of the WTO agreements related to sanitary measures and food; and, some text is redundant and could be eliminated in favour of issuing enabling regulations instead.

The draft proposed Food Law proposes a "Single Food Safety Agency" for policy and control operations, by establishing a Food Institute which is the ultimate food references center (a center of excellance, if you will) in Jordan. This concept is receiving wide reaching

consideration in many countries of the world and will assuredly be the trend in the futhrer. If Jordan carrys this out, they will be at the "cutting edge" of the trend.

The provisions of the law are comprehensive, however do have gaps which need to be address. Definitions are limited and will require additions and some defiitions may require revisions. Authority granting statements need to be added and task statements for the Borad of the Institution need to evaluated, in light of the authorities granted to the institution which do not appear in the task statements. A few operational activites need to be added to fill in needed food control measures.

Absent from the law are any references to the primary principles of sanitary measures, and required procedures specifically addressed in the WTO/SPS Agreement. The principles of the basic rights of Members, harmonization, transperancy, equivalency and non-discriminatory trade practices and the procedureal requirements for notification and risk assessment need to be addressed. This can be done by assuring the texts of the articles reflect these principles and that authority is granted to prepare procedues and establish requirements for those operational activities in the agreements.Because of the importance of some of these principles, namely the basic rights of Members, non-discriminatory trade practices, and equivalency, it may be prudent to develop separate articles to the law to specically address them.

It is the considered opinion of this consultant that the proposed draft food law would be a more suitable starting place for developing a final food legislation. By including the suggested changes listed in this report, it is considered futher that it would provide suitable assurance of food safety to protect consumers, and conform to the international requirements of food safety established by existing WTO international trade agreement.

Scope of Work for Conformity with the WTO Agreement on Sanitary and Phytosanitary Measures-Food Aspects

General Tasks of the Consultant.

The Consultant shall:

Throughout the consultancy, ensure good communication with AMIR management. The consultant should provide verbal updates to the AMIR management at least weekly; and,

Ensure that AMIR management is informed immediately of any material problem, which will compromise the integrity of the consultancy, its data or its implementation time frame.

Immediately report to the Head of the Policy Component any bottlenecks/obstacles in the process of enacting/adopting proposed legal measures.

Tasks Related to Understanding the Challenge(s) Specified in Section II above.

Review the deliverables of Milestone 21 under policy component (Year 1)

Tasks Related to Addressing the Challenge(s) Specified in Section II above.

The tasks the Consultant will perform under this Scope of work shall include, but not be limited to, the following:

Review the Law on Public Health and the draft Law on Food Safety; determine where provisions connected with conformity to the WTO SPS should be addressed; and draft legal measures to conform to SPS food safety aspects. Legal measures could be amendments to the Law on Public Health, amendments to the draft Law on Food Safety, and/or a totally new law to conform to SPS food safety aspect.

Reporting Tasks

.

The Consultant shall provide the following:

A short report on non-conforming aspects of the Law on Public Health and the Draft Law on Food Safety with the WTO SPS requirements.

Legal measures to conform to the SPS Food Safety aspect. Legal measures could be amendments to the Law on Public Health, amendments to the draft Law on Food Safety, and/or a totally new law to conform to the SPS food safety aspects.

If the expert is not a lawyer, he or she should provide language, which is clear enough to be mapped into Arabic Legal language.

The Consultant shall deliver the report to the AMIR Program office in draft via e-mail at the following addresses: farhat@amir-jordan.org and swade@chemonics.com

Within one week of receiving comments on the draft report from the AMIR Program office, the Consultant shall produce a final report and deliver it to AMIR Program office (via Chemonics International, Inc. headquarters in the case of U.S.-based consultants) in the following manner, unless otherwise specified in writing:

On a 3 ½" diskette in Word Perfect 6.1 format;

As an attachment in Word Perfect 6.1 format via E-mail to pbittner@chemonics.com, jdorr@chemonics.com, dbrown@chemonics.com, ymustafa@chemonics.com farhat@amir-jordan.com, and swade@chemonics.com

The Consultant carried out the assigned activity beginning on June 10 and completeing by July 3, 1999, utilizing the english translations of both laws which was provided by the AMIR Program management. A copy of each law is attached as Annex 1 and Annex 2 to this final report.

Reviwe of Law No. (21) for the Year 1971 Public Health Law

In Jordan, the existing Law No. (21) of 1971 for Public Health is the primary law for controlling public health matters including those aspects of food control related to public health. Other laws in place, which address specific food control requirements, include Law No 15 for the Year 1994, Law of Standards and Metrology (which is believed to be under redrafting at this time); Law of Agriculture and the Law of Marketing Agriculture Products.

A review of the Public Health Law by this consultant concluded that the food control provisions are significantly lacking in substance and are out-dated for today's food safety and quality standards for most national applications and irrelevant for international trade requirements. The following specific comments are offered on any of the provisions of this law that could be applied to food, food production, food quality and safety, and marketing, trade practices and fraudulent handling of food.

Chapter Four

Article 10: This provision relates to control of certain foods which may be the source of contagious disease in man, specifically, vegetables, milk and its products, and "any other food stuff that can be a contagious source". Health officials are provided authority to take all measures necessary as a precautionary measure or to control or stop the disease. The diseases include Cholera, typhoid or paratyphoid, dysentery or "any other contagious disease". With a stretch of the imagination, this provision might be considered as a means to control food from import sources as an SPS measure however, without specific text providing specific authority it would not be considered suitable for this purpose. The provision does not provide sufficient detail as to the means for assuring the products are infected, is a causative agent in the disease transmission, disposition of the products once they are proven to be the causative agent, etc. The provision is focused principally on the control of the disease rather than the control of the food to prevent the disease.

Article 13: This provision covers the spread of disease from human waste, or private or public sewage in "any place" which presumably applies to food factories and food service establishments. Appropriate health facilities are to be maintained by order of the health authority. This provision could have application to the suitability of sewage and human waste systems in food establishments and food factories, however provides little to no detail on specific requirements for food establishments to be meaningful and useful in food control.

Article 14: This provision pertains only to dairies and their products. The health officials have authority to prevent the distribution and sale or consumption of dairy products after discovery that they are "polluted or represent a health damage". The provision does require the implementation of an inspection, results of analysis or reliance on other trustworthy news. The authority is too limited to be meaningful since inspection is not defined (inspection of the product, or the factory) and the fact that post problem inspections rarely identify a problem which can result in identifying either the source of a problem or confirm a health hazard. "Polluted" is not an appropriate term in today's law since it implies a source, usually chemical contaminant, emanating solely from an industrial or an environmental source. This may be a reflection of translation from Arabic to English.

Chapter Eight

Article 27: This provision relates to "clean" maintenance of real estate, which by definition includes land and buildings etc. regardless of purpose. Although the provision speaks of persons residing in the village, the text is sufficiently vague and non-specific that it could apply to buildings used as factories for food or other food service, although it appears to be directed to residential real estate. In either case, the provision is totally unsuitable for application to the "clean maintenance" of food establishment.

Chapter Nine

Article 30: This provision defines Health Loathsome Sites and nearly all items defined could apply to food production or service facilities. However, the provision only identifies the conditions that causes these sites to be considered "Loathsome", many of which do not normally pertain to food establishments. None-the-less, if a site in and about a food establishment should meet the specified conditions, action could be taken by health authorities under this provision to cause correction or impose sanctions and penalties. Penalties for having caused the offensive condition are prescribed in Article 31. The provision is too general and broad to apply to food quality and safety aspects of food production or food service in this time.

Article 31: This provision prescribes the penalties for creating the offensive conditions at the site and provides authority to the Health Authority. Although this provision could be used in the case of a poorly maintained food establishment, its text is too vague to be suitable for such purpose.

Chapter Sixteen

Article 63: This provision provides the definitions for various terms used in this Chapter, which is solely related to foodstuff and drugs. Pertaining to food, only the terms, food, person, additives and label are defined. These terms provide acceptable definitions for the terms however they apply to the terms at the time this law was implemented. From the time this law was prepared, there has been development of advanced food technologies, exceptional development of the numbers and types of food products, advances in science allowing for more sophisticated assessment of food hazards and greater sensitivity in detection of hazards. These advances require the definition of a number of terms not used in the law, simply because of its age.

Article 64: This provision defines "cheating" for foodstuff. This term appears to have the same meaning as the term "Adulteration" found more commonly in western food law. This may also be a translation problem from Arabic to English. However, most of the items listed relate to food safety in terms of contaminants, residues, processing, transporting and storing conditions which present health hazards, container and packaging safety, exposure to radiation, etc. The items listed in this article cover the standard expected types of circumstances, situations and conditions considered by most food laws as meeting the definition of a food being adulterated. It does not cover the addition of color or other food additives that are not approved, or at levels exceeding established use levels. It does not cover the contamination with filthy substances such as vermin excreta, or pesticides, which are not permitted or exceed, established residue tolerance levels. It does not cover the packaging and container safety and prohibit the use of materials in container and packaging materials that will result in unsafe food.

Article 65: This provision pertains to the food labeling and identifies what is considered fraudulent. Most of the items listed under this provision are standard requirements, except the provision does not require a statement of ingredients in the order of preponderance,

does not require any warnings for misuse or directions for proper use. It does not clearly state that a label is required on all packaged food products.

Article 69: This provision describes the authority of the Minister of Health related to food, including the right to issue a written order to prohibit selling "cheated" or "fraudulent" food. It includes issuing regulations on imported foods, provided certain conditions are met; and, can seize products that do not comply with the first two items under this provision just mentioned. The Minster is not provided sufficient rights to maintain control as needed, specifically in matters related to food safety and new technologies. It does not provide authority to approve food additives; and does not grant the right to delegate this authority to other appropriate members of the staff of the Ministry entrusted to carry out the responsibilities under this law.

OVERALL ASSESSMENT

This consultant's overall assessment of the current Public Health Law as a means of governing food quality and safety is, that in this day and time, the law does not meet current legal standards of acceptability. The consultant finds insufficient substance in the text of the those provisions that relate to food, even to serve as a bases for redrafting the law to meet acceptable legal standards and meet requirements in today's operational food control environment. The consultant agrees totally with the decision of the government to draft a new law solely for food, separate and apart from other legislation, and for the purpose of administering food control programs to assure food quality and safety from both domestic and foreign sources.

REVIEW OF DRAFT LAW ON FOOD (No. ---- for 1998)

The proposed draft food law (copy attached) was reviewed by the consultant for its completeness and currency with today's legal thinking for national administration of food quality and safety and for the facilitation of trade, both nationally and internationally. The following specific comments are offered, including alternative texts, additions and omissions, as recommendations to be considered. The consultant recognizes fully that the translation of legal text from one language to another can often create confusion, misinterpretation, and misunderstanding and in some cases can be completely divergent to the intention of the text. During the course of this review, many terms are used that do not seem to fit the context and in these cases, the consultant points out that the case may be due to translation problem with the two languages. Therefore, any alternative text or new text offered as a suggestion may require discussions between the drafters and the consultant to determine the exact meaning of the article or paragraph in question and the appropriateness of the suggested change. This would assure the proper understanding as to the intent of the original text is achieved before translation occurs back to Arabic.

Article 1: No Comment

Article 2, **Part One:**

Item 1: Although the term "institution" is listed as the Public Institution of Food, it may be useful to identify the superior organizational unit in which this institution is to be located, unless it is to be an autonomous, independent unit of government unit without a superior unit. If it is be a part of the Ministry of Health, it is suggested that the Institution be identified as such. This information could be included at this point or in Article 4 or 5 of the law.

Part Two

The term **Food** should indicate that it includes any stuff used as ingredients as well as in manufacturing, mixture or preparation.

The term **Special Foods** should include any food considered to be a "functional food", or other foods which make claims for health improvement.

In the definition of the term **Food Additive**, the term "polluting agents" is use. This may be a problem with the translation from Arabic to English, but it appears to have the meaning more commonly referred to in English as "contaminants". The term polluting agent in English is generally considered to be contaminants from environmental and industrial sources only. Food Additives should be free of contaminants or within acceptable limits established for contaminant, regardless of the source. If this is well understood in Arabic, then the English language version will need to be more explicit for better understanding by English readers of the law. The same comment applies to the terms "chemical exterminations" which appears to have the same meaning in English as "Chemical Pesticides".

The term **Quality** is suitable for this legal document. It should, in practice, mean the totality of the food attributes, which makes it legally acceptable for consumption by humans. This includes the safety of the food at the time of consumption and the physical attributes such as size, color, shape, etc. Separating the judgement of the acceptability of food into two categories, that is food that meets acceptability on quality attributes and food that meets acceptability safety attributes causes confusion in the trade and for the consumers. It also creates divisiveness of food control organizations at the national level over jurisdiction and legal responsibilities. By including food safety as a component of the total quality of food, with quality being the superior indicator term and representing the total condition of the physical and safety characteristics of food in this law will prevent these problems for Jordan in the future.

The term **Polluting Agent**, the comment above related to food additives applies.

The term **Circulation** is not commonly used in English as a term to mean distribution. However, since the term "distribution" is included in the definition, it should be clear to English readers of the law as to it meaning.

The term **Standard** perhaps should make reference to the official national compendium of food standards such as that which has been established and adopted for mandatory and voluntary use by JISM. It may also be advisable to include specific reference to the standards established and adopted at the international level by the Codex Alimentarius

Commission. This addition would establish the law as a link to the Agreement on Sanitary and Phytosanitary Measures of the WTO.

The term **"Announcement"** is defined and appears to have the same meaning as used in English western law as Advertisement. If this is the case, then it is suggested that the following revision be made to cover the most prevalent misrepresentation method, which is the oral misrepresentation done extemporaneously by promoters who do not follow approved texts or "scripts" designed for promotion purposes. The revised sentence would then read, "…whether presented orally, read, using audio or visual methods or aid, or presented extemporaneously for the purpose of promoting, selling or dispensing the food directly or indirectly.

The first definition of the term **Food Safety** relates to the use and purpose of the food. All food should be safe regardless of its intended purpose or use. Labeling information should provide the user with appropriate instructions on the proper use of the product and these requirements should be elaborated as part of the labeling requirements of the law. Consequently, there is no need for this definition for this purpose.

The second definition of the term **Food Safety** is too detailed and as a result can be interpreted as covering only those public health safety issues mentioned in this definition and not any others. The definition should only state that food should not be hazardous to human consumption and within acceptable levels of risk established through acceptable risk analysis procedures and based on sound scientific evidence. There should not be but one definition in the law defining Food Safety and it should be along the lines described here.

Several following terms are used in this law that may require definition. They include the following:

Council
Corporation
Validity
Chemical Extermination Agents
Publicity
Animal Food or Animal Feed (only if this law is to cover the safety of animal food or animal feed when used to feed animals used for human food production)

Article 3, Part 1 & 2: No comments.

Article 4:

The Institution will have authority over all food to ensure "validity" for human consumption. Is the term "validity" intended to include food quality and food safety attributes? Does it include "fitness for consumption"? Is it a term intended to be used for the purpose of sanctioning or approving food for distribution? It appears that it also includes food locally manufactured "for any purpose", which would mean that it includes food manufactured for **export** purposes. The authority also includes protection of consumers against cheating and fraudulent "descriptions" of food, which **does not necessarily cover** fraudulent marketing,

sales or trading practices. It is suggested that fraudulent marketing, sales and trading practices should be covered in this law. This may be an aspect that should be considered unless covered elsewhere in other legal instruments.

It also points out the need for defining the term "validity" in the definitions section of Article 2.

Article 5, Part One:

The opening statement could be more positively stated as an authorizing statement. Instead of the Institution "assuming" the listed tasks and power, the more positive statement would state, the Institution "is authorized" to assume the powers and to carry out the tasks listed below. This may be a matter of translation from Arabic to English.

Item 2, Inspection authority should also include food storage facilities such as food storage warehouses and import/export sheds, go-downs, and any facility or real estate used in handling or storing food.

Item 3, The final statement granting the Minister authority to issue regulations related to imported foods should be listed as a separate authority and cover all of the tasks expected of the Institution (Items 1-9 and any other items added to this Article). Regulations will be needed to establish acceptable procedures and requirements for nearly all the tasks listed. It is suggested that the additional items be added to this Article to include the Authority to the Minister to "prepare and issue regulations, directives and guidelines, as necessary, to establish policy, procedures and requirements related to all tasks listed as the responsibilities of the Institution".

Item 4, The term "shall be adopted" appears to have the same meaning as "shall apply". The term "**food to be prepared again**" is more commonly referred to as "Reconditioning" in English. Both these comments may be a problem related to translation from Arabic to English.

Item 5, This item may be considered as a trade barrier in that the so called "validity date" does not always mean the product is unfit for consumption at that time. In fact, most food enterprises set conservative dates for fitness of their products to avoid problems with liability from consumer complaints and validity dates apply principally to quality aspects and not necessarily to safety aspect. Safety issues are with food at all times. Constant scrutiny is required to assure food does not become unsafe at any time regardless of the validity date.

The validity date has no bearing on these issues. Unless there is to be specific requirements for Jordan to be provided with shelf life studies data confirming the ultimate shelf period before entry approval (which can be a trade barrier), this provision would be difficult to defend scientifically on the bases of risk analysis. Jordan would have to prove the product is unsafe for use after the validity date, which would not be possible since the product validity date is not yet passed at the time of entry. However, the date could be used as an indicator of the time when the producer can no longer guarantee quality factors of the product.

Item 6, The item grants authority over the publicity of food, which appears to mean food promotion and advertisement. If this is the case, the term, "Publicity" or "Advertisement" should be defined as to its meaning in Article 2. There is confusion in this aspect, since the term "Announcement" is defined in Article 2 as promoting, selling or dispensing food directly or indirectly. If the terms Announcement and Publicity are different, they should be separately defined.

Item 7, The term "quality' appears for the first time in the draft law in this item. It is encouraged that the term quality reflect the traditional meaning related to appearance, shape, size, color and other physical characteristics of food, **but should also include attributes of food safety.**

Item 8 and 9, no comment.

The consultant suggests the additional tasks listed below be added to the draft, as important control mechanisms needed in food control. They are as follows.

Authority to collect and test food samples. The Minister or his delegate should have direct authority to collect food samples from any source and at any time and anywhere the product appears, whether or not it is being offered for sale. The samples may including ingredients, additives, intermediate and in process materials (including scrapings, manufacturing debris, and other material) found within a food factory, transport, storage, handling, service and anywhere food is found to be present.

Recall Authority. The Minister or his delegate should have the authority to order a product to be recalled from the market. The specific mechanism for this procedure can be further elaborated in regulations, which allow for the depth of the recall to be at different levels of the market, depending on the severity of the need to remove it from the market. Recall would be at the owner or producer's expense regardless of the level of the recall, from the wholesale level to the level of the consumer, when warranted due to safety considerations. This allows for immediate action to remove food products from the public domain that pose potential or imminent danger of injury, sickness or death.

Approval of color and food additives. There is no statement that the Minister or his delegate has prior approval rights on color or food additives, added to food intentionally for technical reasons at the domestic level. The authority would also be extended to imported products to assure only approved additives are used in the products entered for commerce in Jordan. Although most foods in international commerce contain food additives that have been approved at the international level, domestic use of additives may need to be assessed as to their safety risk, as well as imported products where doubt is involved.

Authority to issue regulations: As indicated in comments on item 3 above, the Minister or his delegate should be granted blanket authority to establish and issue regulations, directives and guidelines on matters related to food under the responsibility of the Institution.

Article 5, Part 2.

The consultant encourages the term quality to be inserted in this paragraph to read "…with regard to affairs of food control, quality and safety assurance, nutritional value…"

Article 6, Part One:

The Minister or his delegate should be provided authority to issue rules of proceedings for the conduct of the meetings, including the conduct of the representatives, the voting procedures, agenda control, and other matters to allow for the efficient and effective management of the Board Meetings.

Article 7, No comments.

Article 8, The Board appears to be assigned the task of functioning as an executive body of the Institution. Consequently, the tasks assigned to the Board should have their foundation in the tasks assigned to the Institution. This does not occur when comparing the Institutional tasks in Article 5, with the tasks for the Board in Article 8. The consultant can not determine if this was intentional, perhaps to limit the powers of the Board to only those items listed in Article 8, or a matter that was not recognized by the drafters of the proposed law an the time. Examples of differences are:

No tasks are assigned to the Board related to the Institutions responsibility to cooperate with JISM in establishing national food standard.

The Board is to issue health regulations and conditions necessary for food control, yet the Institution's task do not mention anything about having the authority to issue or develop health regulations related to food control. If a broad interpretation is given to the Institutional objective as stated in Article 4, one might say that the Institution would have as an objective to do everything needed to control and supervise food, which would include the issuance of health regulations. However for clarity purposes, it should be explicitly stated as a task.

Three of the nine tasks listed for the Institution (Part 1, Items 3, 4, 5) deal almost exclusively with imported food control, whereas, none of the tasks assigned to the Board appear to have anything to do with imported food products.

Specific Comments on the tasks assigned to the Board

Article 8: Part One

Item 1, No comment.

Item 2. Issuing health regulations is different from developing these regulations. From the text of this item, it appears the Board would be in a position to approve and authorize the

issuance of the regulations, but not the development. The Institution does not have the explicit authority to develop the regulations. The consultant recommends strongly that the operational experts within the Institution, in collaboration with other relevant experts in and outside of government, be involved with the development of technical regulations. Review and approval of the proposed regulations should be the responsibility of the Director General at the Institutional level and then by the Board, as a two-tier level of approval process. In some countries, the regulations are issued as a proposed regulation in the formal government announcement (publication in the National Gazette) with a period of comment from the public and interested parties, which are then considered before a final regulation is issued. The regulation would then be issued under the Ministers final authority.

It is difficult to establish appropriate procedures for the issuance of regulations, unless they exist already as part of the government's administrative rules of procedures. One of the important aspects of the issuance procedures is to prevent the procedures from becoming a barrier in the process and causing an undue delay in the process. In any case, the procedures should be left to regulations or rules of procedures and should not be written into law without specific need to satisfy specific purposes.

Item 3, The Consultant is not familiar with the requirements in The Law of Crafts and Industries No. (16) for 1953 (article 12), however if they are rules of procedure to secure a license to operate a business they would not involve technical requirements. However, one of the legal actions that can be taken in any licensing system is the government's ability to suspend or revoke an operational license. This opportunity should not be missed and the authority to grant licenses and to establish the requirements to maintain a lawful license should be a function of the Institution. Equally, authority to suspend and revoke as necessary any license with cause should be granted.

Item 4, no comment.

Item 5, A system of laboratory accreditation is currently under review by JISM and there should not be any conflict in jurisdiction or responsibility between the Institution and JISM related to laboratory certification or accreditation. Accreditation should comply with internationally accepted standards.

Item 6, 7, & 8, no comment

Part two

The membership of committees formed to assist the Board in carrying out its assigned tasks is restricted to Board members only. The consultant suggests that if the committees are to relate to the technical tasks listed in items 2, 3, 4, 5, & 6, then the Board may be better served by requesting the Functional Committee to undertake these activities. The Functional Committee should utilize experts, as needed, both within and outside government, including industry, and be allowed to include such experts in the committee as advisors, or invite their advice in writing or through oral presentations made during the meetings. No voting privileges would be authorized for those experts serving as advisors to the Committee.

Article 9 Part 1

Item 1. Depending on the qualifications of the specialist in Preventive Medicine, consideration should be given to including a specialist in human toxicology from the Ministry of Health as an additional member to the Committee.

Item 2. Consideration should also be given to include a Plant Pathologist or Plant Biotechnologist from the Ministry of Agriculture to address the issues related to food from plant origin and food derived from new and developing biotechnology.

Items 3 – 8, No comment

Part Two

Item 1-4, No comment

The consultant suggests that an additional power be added to the functional committee, and that is the right to call upon experts outside the Institution on technical issues for advice and information to consider in the formation of their recommendations.

Article 10, Part 1-3: No Comment

Article 11, The authority to approve food additives should be added to Article 5, as previously discussed.

Article 12, It may be necessary to further elaborate this provision by indicating from whom this license is to be obtained. For instances, is the license to be obtained from the Institution, local authority, Health Officers, etc?

Article 13, In this case does the term "**handling"** encompass all aspects of food "circulation". Since the term circulation is defined in Article 2, it may be a better term to use here than handling.

Article 14, Part One:

This article mentions the safety of food for animal health. The law makes no reference to food intended for animals elsewhere and the definition of the term "Food" (Article 2) does not include food for animals. It may not be the intention of this law to have authority over food used for animals and it may be this control is already well established in other law and under the jurisdiction of other government control agencies (Ministry of Agriculture, Veterinary Services). The consultant suggests that if other legal instruments already control food for animals, this proposed law should be reviewed in terms of its compatibility with the provisions of the other law. Secondly, reference should be made that food for animals are to meet the requirements of these other laws before being used for animals used to produce

food for human consumption. The reasons are that food used for animal used in the production of human food can and often are a source for human health hazards from human food.

The draft food law prohibits the presence of hormones as residues in human food. Recent WTO dispute panel decision rendered this type provision as a trade barrier. However, the decision is not yet final due to appellate proceedings, but the scientific evidence still supports the safety of the specific hormone residues involved at or below the established international residue levels. Consequently, the consultant recommends that the item be revised to include the statement "when they exceed established national limits or the international limits when they differ from national levels."

Part Two:

As indicated in previous comments, the approval authority for food additives may need to be added to the tasks and authorities of the Institute under Article 5 to prevent any serious question as to jurisdiction when trying to enforce this provision.

Part Three; No Comment

Part Four:

This provision should incorporate the concept of Good Manufacturing Practices"(GMPs), a body of regulations which identify appropriate procedures, processes and activities which embody food quality and food safety practices, including the use of Hazard Analysis and Critical Control Point (HACCP) based systems in an overall quality assurance program. It is suggested that the provision be amended to include the GMP and HACCP concept by adding the phrase "or was manufactured, processed or packed under conditions other than Good Manufacturing Practices requirements". These requirements can then be established as regulations.

Part Five: No Comment

Part Six:

This provision would normally be covered as part of the GMP/HACCP requirements. If the GMP/HACCP provisions are not to be included as suggested above, then the provision should be amended to also include the quality and safety of packaging materials.

Part Seven through Part Eleven: No Comment

Article 15,
Part One through Three: No Comment

Part Four:

This provision lacks a requirement normally required in all countries and especially in international trade. A statement should be added to the itemized list of what is required on the label to include a label statement as to the quantity of the contents in terms of weight, measure, or numerical count.

Part Five: No comment

Part Six.

The consultant is not sure of the meaning or the requirement of this provision and consequently can not comment without further explanation or discussion.

Article 16: No Comment

Article 17, Part a: No comment

Part b, 1:

The Minister is to render his decision on any objection filed against the action taken by the Director-General of the Institute under the provisions of items 1-7 of paragraph (a) of this Article. The Minister is to consider the recommendations of the functional committee in this process. He has 21 days to render the decision and the functional committee meets one time per month. It may be advisable to extend this time to 30 days, to keep the functional committee from having to call special meetings all the time due to the volume of actions that maybe contested.

Part b, 2: No Comment

Part c. 1:

This provision provides authority for the Director General of the Institute to "damage" (assumed to mean the same as the word - destroy) meat and dairy products when proven to be unfit for food. The criteria for this determination include "clinical" examination done by a public health doctor or a veterinary doctor or upon a laboratory report issued by the Institution's laboratory. The consultant questions the inclusion of either the public health doctor or the veterinary doctor as experts in the field of food technology and should not be making decisions in this field without qualifications in the appropriate disciplines. In addition decisions by the Director General on important issues that can result in product destruction and property loss to producers and may end up in a court proceeding, should not be based on the results of an unspecified "clinical" test. Clinical testing generally relates to patient testing or testing of specimens collected from patients. The clinical tests may serve as evidence of sickness or injury and confirm a causative agent, which can be correlated with the evidence from the food testing, which should be performed at an official laboratory using approved methods. An authorized officer qualified to perform such tests, using officially sanctioned analytical methods should carry out all official food testing.

The consultant suggests that only approved official analytical methods be used in official food control for food analysis by official officers of the institution or by accredited laboratories certified for food analysis according to national or international specification for laboratory quality assurance. This is extremely important when the matter may be referred to the courts for adjudication.

Part c.2: No comment.

Part Four and Five: No comment.

Article 18, Part One:

The reference to "working hours" in this provision should be considered to be anytime that the factory is functioning.

Part Two, Three and Four: No Comment.

Article 19 - Article 27: No Comment.

Consultant's Conclusions

The draft proposed law is a good law and would meet the international requirements. It appears to the consultant that it would generally allow the necessary controls to be set in place to adequately address the requirement of meeting international agreement obligations as a Member of the WTO. The consultant has made specific recommendations that should be considered to revise the draft law. If further details or explanations are needed, they can be provided.